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<b>TO:</b> Mr. John Kittle	<b>FROM:</b> Scott A. Burow	<b>RECEIVED</b> CENTRAL FAX CENTER
<b>COMPANY:</b> Commissioner for Patents Mail Stop Petitions	<b>DATE:</b> September 21, 2004	<b>SEP 21 2004</b>
<b>FAX NO.:</b> 703-308-3139	<b>TOTAL NO. OF PAGES:</b> (including cover sheet) 18	
<b>YOUR REFERENCE NO.:</b> 10/005,789	<b>OUR REFERENCE (C/M) NO.:</b> 011738.00038	
<b>RE:</b> Petition to Withdraw Holding of Abandonment Pursuant to 37 CFR § 1.181		

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<b>NAME:</b> Shannon Salamone	<b>PHONE:</b> 312-463-5568
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**COMMENTS:**

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CHICAGO

WASHINGTON, D.C.

BOSTON

PORTLAND, OR

Appln. No.: 10/005,789  
Amendment dated April 27, 2004  
Reply to Final Office Action mailed March 3, 2004

19. **(Previously Presented)** The system of claim 7, wherein the cell maintainer comprises vitamin A derivative retinoic acid.

20. **(Previously Presented)** The system of claim 1, further comprising a second medicament composition contained within the reservoir configured to foster the development of cells which produce exogenous substances at the target site.

21. **(Previously Presented)** The system of claim 1, further comprising a second medicament composition contained within the reservoir configured to use native cell structures at the target site as a framework on which to grow living cells.

22. **(Previously Presented)** The system of claim 1, wherein the medicament composition is configured to use the native cell structures at the target site as a framework on which to grow living cells.

23. **(Previously Presented)** The system of claim 1, wherein the medicament composition is configured to foster the development of cells which produce exogenous substances at the target site.

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### **REMARKS/ARGUMENTS**

The Office Action of March 3, 2004 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested.

Independent claim 1 and dependent claims 2, 4-7 and 18-23 are pending. Claims 1, 2, 4, 20-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Rise (U.S. Pat. No. 5,643,203) in view of Seckel (U.S. Patent No. 5,584,885). Claims 5 and 6 were rejected under U.S.C. § 103(a) in over Rise in view of Seckel and in further view of Hadden (U.S. Pat. No. 5,632,983) and Masters (U.S. Application No. 2003/0007991). Claims 7, 18, and 19 were rejected over Rise in view of Seckel and in further Medenica et al. (U.S. Pat. No. 5,738,129). The applicant respectfully traverses the rejections of claims 1, 2, 4-7 and 18-23 and submits the following remarks.

### **Use of Masters as a Prior Art Reference**

The Office Action states that Masters claims priority to application 09/160,424 which has a filing date of September 25, 1998. While not admitting that a filing date of September 25, 1998 would qualify a reference as prior art, the Applicant respectfully submits that Masters is a continuation-in-part from the 09/160,424 application. The Office Action did not suggest that the application, S/N 09/160,424, would support a 35 U.S.C. § 103(a) rejection. Thus, as the full subject matter of the Masters reference can only claim priority to the August 3, 2000 filing date, it appears that the Masters reference cannot fairly be considered prior art for the current application under 35 U.S.C. § 103(a). Therefore, withdrawal of any rejection based on the Masters reference is respectfully requested.

### **Rejection Under 35 U.S.C. § 103(a) – Rise in View of Seckel**

Claims 1, 2, 4, 20-23 were rejected under § 103(a) over Rise in view of Seckel. Seckel is directed towards the growth of biological tissue. Seckel states:

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The present invention provides a regeneration chamber for promoting and controlling the growth of biological tissues.

(Seckel, Col. 3, Ln. 56-57). Thus, Seckel teaches the use of a chamber for controlling the growth of biological tissue. The Applicant has reviewed Seckel and has been unable to find any reference to any embodiment that does not use a chamber. If the Examiner disagrees, the Applicant respectfully requests that the specific location in the Seckel reference that discloses the use of catheter be reference pursuant to MPEP 706.02(j)(A).

Nor is the Applicant aware of any teaching in the Seckel reference that suggests that Seckel would be suitable for use with a catheter. In contrast to the teaching of Seckel, claim 1 recites "implantable infusion device for delivering a medicament composition to a target site in the living body through a catheter" with "the medicament composition including living cells." The Applicant respectfully asserts that, unlike claim 1, Seckel teaches away from the use of a catheter because a chamber with an inlet and outlet port is always used:

The exit flow path through Output Port 16 further provides a pressure relief path which allows agents and other substances in Chamber 12 to flow from Chamber 12 through Output Port 16 when pressure in Chamber 12 increases. The pressure in Chamber 12 may increase, for example, when new agents are injected through the Input Port 14 or because of the accumulation of byproducts from the regeneration process. Output Port 16 thereby prevents the occurrence of pressures within Chamber 12 that would be detrimental to the healing and regeneration process or possibly even force Proximal End 18 or Distal End 20 of Nerve 22 out of the Chamber 12.

(Seckel, Col. 6, Ln. 3-14). Therefore, the use of a catheter would be contrary to the invention disclosed in Seckel. Moreover, using the present application as a road map to combine Rise and Seckel to achieve the present invention is improper hindsight reconstruction.

Thus, the Applicant respectfully submits that nothing in Seckel suggests the combination of Seckel with Rise nor is there any indication that such a combination would be successful. See MPEP 706.02(j) ("To establish a *prima facie* case of obviousness, three basic criterion must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success."). As

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Rise cannot properly be combined with Seckel, the combination of Rise and Seckel cannot make obvious claim 1. Moreover, Hadden and Medenica do not overcome the deficiencies in the teachings of Seckel and Rise. Therefore, the Applicant respectfully requests withdrawal of this ground of rejection.

Claims 2, 4-7, and 18-23 depend from claim 1 and are nonobvious for all the above reasons and because of the additional limitations recited therein. Thus, the additional rejections of the dependent claims are respectfully deemed moot in light of the traverse of the rejection of claim 1.

### CONCLUSION

It is believed that no fee is required for this submission. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 19-0733, accordingly.

All rejections and objections having been addressed, Applicant respectfully submits that the instant application is in condition for allowance, and respectfully solicits prompt notification of the same.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: April 27, 2004

By:



Scott A. Burow

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**Notice of Abandonment**

Application No.

10/005,789

Applicant(s)

HART, AUB JEROME T.

Examiner

Art Unit

Kathryn L. Thompson

3783

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address—

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 03 March 2004.

(a) ☐ A reply was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply (including a total extension of time of \_\_\_\_\_ month(s)) which expired on \_\_\_\_\_.

(b) ☐ A proposed reply was received on \_\_\_\_\_, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.

(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) (with fee) under 37 CFR 1.114.)

(c) ☐ A reply was received on \_\_\_\_\_, but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).

(d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-65).

(a) ☐ The issue fee and publication fee, if applicable, was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-65).

(b) ☐ The submitted fee of \$\_\_\_\_\_ is insufficient. A balance of \$\_\_\_\_\_ is due.

The issue fee required by 37 CFR 1.18 is \$\_\_\_\_\_. The publication fee, if required by 37 CFR 1.18(d), is \$\_\_\_\_\_.

(c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowance (PTOL-37).

(a) ☐ Proposed corrected drawings were received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply.


(b) ☒ No corrected drawings have been received.

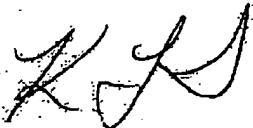
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

The letter of express abandonment which is signed by an attorney or agent acting in a representative capacity under 37 CFR 1.201(a) from the filing of a pending application.

5. ☐ The decision by the Board of Patent Appeals and Interference rendered on \_\_\_\_\_ and because the period for seeking court review of the decision has expired and there are no allowed claims.

6. ☐ The reason(s) below:

  
NICHOLAS B. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700



Requests to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to maintain the application in effect on patent term.

PTOL-1432 (Rev. 03-01)

Notice of Abandonment

Part of Paper No. 09042004



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